REMARKS

Claims 4-5 and 8-18 are presently pending. Claim 11 has been allowed. The Office Action indicates that claim 14 would be allowable if rewritten in independent form. None of the claims have been amended or cancelled. Thus, claims 4-5 and 8-18 remain pending in this application.

Claim Objections

The Applicants note that the status identifier for claim 4 in the Amendment in Response to Final Office Action Dated March 23, 2007 with RCE (the "previous Response") incorrectly stated that the claim was (Previously Presented). As the Office Action notes, the correct status identifier for claim 4 should have been (Currently Amended).

Claim Rejections - 35 U.S.C. § 103

Claims 4-5, 8-10, 12-13, and 15-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,828,716 to McEwan et al. ("McEwan") in view of U.S. Patent No. 3,508,653 to Coleman ("Coleman") in view of U.S. Patent No. 6,074,883 to Kelly et al. ("Kelly") in further view of U.S. Patent No. 5,354,483 to Furse ("Furse").

Many of the rejections made in the current Office Action are identical or nearly identical to the rejections of the previous Office Action dated March 27, 2007. *See* Office Action, p. 3, para. 2-3, p. 5, para. 1-2. Those rejections were properly responded to by the Applicants in the previous Response. The current Office Action does not properly respond to any of the arguments Applicants made in that Response.

The Applicants note that the Manual of Patent Examining Procedure ("MPEP") § 707.07(f) states, "Where the applicant traverses any rejection, the Examiner should, if he or she repeats the rejection, take note of the applicant's argument and **answer the substance of it.**" MPEP, Incorporating Revision No. 6, September 2007, § 707.07(f), p. 700-126. Not doing so fails to accord the Applicants a full and fair opportunity to reply because it leaves the Applicants guessing as to why the Examiner did not find the Applicants' arguments persuasive.

Independent Claim 4

Independent claim 4 is directed toward a method of collecting and separating a patient's blood and recovering a platelet-rich concentrate. The method includes collecting a patient's blood

using "a needle set comprising a hollow needle coupled with a tubing having a fitting adapted to engage a first port in an elongated container fitted with a movable plunger having a second port therein." The blood is transferred from the needle through the tubing, the fitting, and the first port into the elongated container by moving the plunger away from the first port. The blood is centrifuged and separated into platelet-rich plasma and red blood cells, which are displaced by moving the plunger towards the first port and expelling the red blood cells into a waste bag through tubing attached to the first port. Platelet-poor plasma is separated by moving the plunger toward the first port and expelling the platelet-poor plasma through the third port of a plunger rod.

The Applicants respectfully submit that a *prima facie* case of obviousness has not been established because the cited references, either alone or in combination, do not disclose, teach, or suggest, several elements of claim 4.

A. The Applied References Lack "a needle set comprising a hollow needle coupled with a tubing having a fitting", as Required by the Method of Claim 4

McEwan, Coleman, Kelly, Furse, or a combination thereof do not disclose, teach, or suggest a "needle set comprising a hollow needle coupled with a tubing having a fitting adapted to engage a first port in an elongated container", as recited in claim 4.

It appears that the Office Action relies upon McEwan in finding that this element in the four-reference combination. *See* Office Action, p. 3 (stating, "McEwan et al disclose the method substantially as claimed except for disclosing specifically the following: the step of attaching a hollow plunger rod . . . ."). It is still unclear how the needle 36 of McEwan includes "a **tubing** having a **fitting** adapted to engage a first port in an elongated container." Rather, the needle 36 of McEwan is inserted directly into a cap assembly 14 of a blood sample collection chamber 12. McEwan, FIG. 1b; col. 8, ll. 12-15. Thus, the needle of McEwan would have no use for tubing or a fitting. It is, therefore, unclear to which portion of McEwan the Office Action refers when it states, "McEwan discloses a method wherein blood is collected from a patient using a needle set and collected or transferred into a container and **tubing is connected to the container** for delivery and withdrawal of components." Office Action, p. 3 (emphasis added).

Likewise, while the Office Action does not rely upon Coleman, Kelly, or Furse in alleging that this element is obvious, no such needle set is disclosed in Coleman, Kelly, or Furse.

These reasons alone render claim 4 allowable.

B. The Applied References Lack "a first port in an elongated container" in Claim 4

It is unclear on which reference, combination of references, or portion of the reference(s) the Office Action relies upon in finding the elements "a **first port** in an elongated container" obvious. The Applicants respectfully submit, however, that none of the applied references or combination thereof disclose this element.

The chamber 12 of McEwan and the container 20 of Coleman do not include a port or valve. Rather, McEwan's chamber 12 and Coleman's container 20 are simply test tube-like containers being closed at one end and having an opening at a second, opposite end.

Likewise, Kelly's carrier tube 102 does not have a port or valve associated therewith, as does the elongated container of claim 4. The carrier tube 100 of Kelly includes a capillary tube plug 116 having an opening 184 that permits gas inside the capillary tube 114 to escape as blood 182 enters the capillary tube 114, thereby facilitating entry of blood into the capillary tube 114 by capillary action. Kelly, col. 8, ll. 52-58. Thus, the plug 116 functions much differently than the port of claim 4, which may be opened and closed as needed. Present Spec., *inter alia*, p. 5, l. 30 – p. 6, l. 1. One example of a port according to the present invention is a spring-loaded ball seat valve 14 shown in FIGs. 1, 2, and 5a-e of the present specification.

The tube 12 of Furse also does not include a port. Rather, the tube 12 of Furse is sealed by a first closure 14 positioned at a first end and a second closure 16 positioned at the opposite end. Furse, FIG. 1, col. 6, ll. 27-30. The closures 14, 16 of Furse "are similar to **stoppers** of blood collection tubes known in the art" (*id.*, col. 6, ll. 56-57 (emphasis added)) and are "generally made of an elastomeric material such as bromobutyl rubber that reseals after being punctured by a needle or probe" (*id.*, col. 6, ll. 60-62). Thus, Furse does not disclose, teach, or suggest "a first port in an elongated container," as in claim 4.

As such, the Applicants respectfully assert that nowhere do any of the applied references or combination thereof disclose, teach, or suggest "a first port in an elongated container." This is yet another reason why claim 4 is allowable.

C. The Applied References Lack the Acts of "moving said plunger towards said first port and expelling said red blood cells into a waste bag through tubing attached to said first port"

The applied references do not disclose, teach, or suggest displacing red blood cells by "moving said plunger towards said first port and expelling said red blood cells into a waste bag through tubing attached to said first port," as in claim 4.

The Office Action does not address why expelling red blood cells into a waste bag by "moving said plunger **towards said first port**" is disclosed, taught, or suggested in the applied references. As noted in (B) above, none of the applied references include a "first port" in an elongated container. Putting aside this important distinction, in claim 4, the plunger is moved in one direction (away from the first port) to transfer the blood into the container and is moved in an opposite direction (toward the first port) to expel red blood cells. Notably, none of the cited references displace red blood cells by moving a plunger or separating element towards the opening through which the blood is transferred into the containers. On the contrary, the components of the applied references are generally removed by moving the plunger or separating element in a direction **opposite** such opening.

Additionally, the Office Action concedes that McEwan does not disclose "that the separated red blood cells are expelled [sic] into a waste bag." Office Action, p. 3. The Office Action makes no further mention of why this element is anticipated or obvious. The Applicants submit that the reason for this is that it would not have been obvious to expel the red blood cells into a waste bag in the manner of claim 4.

Further still, as discussed in (A) above, none of the applied references have a "tubing attached to said first port", as in claim 4. Accordingly, the applied references – either alone or in combination – do not disclose, teach, or suggest "expelling red blood cells . . . **through tubing attached to said first port**".

In short, the Applicants submit that the applied references do not disclose a waste bag, a tubing, and a first port, much less a waste bag for receiving red blood cells through tubing attached to the first port, as in claim 4. Thus, this claim element is not disclosed, taught, or suggested by McEwan, Coleman, Kelly, or Furse. This is a further independent basis for the allowability of claim 4.

D. The Applied References Lack the Second Centrifuging Act of Claim 4

Additionally, the cited references do not disclose a second centrifuging act wherein platelet-rich concentrate is separated from platelet-poor concentrate, as in claim 4.

The Office Action, like the previous Office Action, relies upon column 14, lines 43-51 of McEwan in stating that "McEwan also teaches that the components may be further separated by centrifugation until desired separation is achieved." Office Action, p. 3. As discussed in the previous Response, this cited portion of McEwan only refers to separation of the "lower density component" from the "denser cellular component." McEwan, col. 14, ll. 46-49. The lighter, low density, non-cellular component is defined by McEwan as serum or plasma while the denser cellular component contains blood cells. *Id.*, col. 11, ll. 25-30. In other words, this statement in McEwan simply refers to separating platelet-rich plasma from red blood cells. Thus, McEwan does **not** disclose "centrifuging said platelet-rich plasma remaining in said container and separating a platelet-rich concentrate from a platelet-poor plasma", as recited in claim 4.

The Applicants submit that Coleman, Kelly, Furse, or a combination thereof also do not disclose, teach, or suggest this element. Thus, claim 4 is believed to be allowable for these reasons as well.

E. The Applied References Lack the Act of "attaching a hollow plunger rod having a third port therein to said plunger and displacing the platelet-poor plasma . . . by moving said plunger towards said first port . . . into a waste bag attached to the plunger rod"

The applied references do not disclose "attaching a hollow plunger rod having a third port therein to said plunger and displacing the platelet-poor plasma" by "moving the plunger towards said first port and expelling the platelet-poor plasma through . . . the third port of the plunger rod into a waste bag attached to the plunger rod," as recited by claim 4.

The Office Action states that "Coleman teaches that the plunger can comprise a hollow rod having a second and third port, i.e. the ports on either end of the axial passageway comprising the plunger . . . ." Office Action, p. 3. The portion of Coleman the Office Action cites in support of this assertion states:

> Should it be desired, the plunger 26 could be provided with a valve type opening which would permit passage of the upwardly moving light phase through the plunger 26 in lieu of, or in addition to, passage therearound. An axial passageway through the plunger 26 could be provided with a valve element, such as a flap valve, for example.

Coleman, col. 6, ll. 63-69.

This portion of Coleman does not disclose "a hollow plunger rod having a third port therein," as in claim 4. At best, the cited portion discloses a valve on the plunger itself, not on the **plunger rod**. The rigid rod 30 of Coleman does not include a port or valve but, rather, is used merely to push down on the plunger 26, causing the plunger to move downwardly, as shown in FIG. 3. *Id.*, col. 6, ll. 49-53. Additionally, nowhere in Coleman is it disclosed that the "rigid rod 30" may be hollow. In fact, because the rod 30 of Coleman must be "rigid" to push the plunger 26 such that the light phase 24 flows around the plunger 26, one skilled in the art would be discouraged from using a hollow rod, as required by claim 4. It also does not appear that the rigid rod 30 is **attached** to the plunger 26, nor would the rod 30 need to be attached to the plunger 26 to perform its intended function of pushing the plunger 26 downward. *See id.*, FIGs. 2-4.

It is unclear what the Office Action refers to when referencing "the plunger rod of McEwan." Office Action, p. 4 (stating, "[I]t would have been obvious . . . to provide the plunger rod of McEwan having a third port therein as taught by Coleman . . . ."). Assuming the plunger rod to which the Office Action refers is the non-rotating rod 44 of McEwan, the Applicants submit that non-rotating rod 44 shares the same deficiencies as the rigid rod 30 of Coleman described above. Namely, the non-rotating rod 44 (1) does not include a port or a valve, (2) is merely used to push the separating segment 18 down the chamber 12 (McEwan, col. 8, ll. 30-34), (3) is not hollow, and (4) is not attached to the plunger.

Additionally, platelet-poor plasma is not displaced by "moving said plunger towards said first port" in McEwan or Coleman. As noted above, neither the chamber 12 of McEwan nor the container 20 of Coleman includes a "first port." Furthermore, unlike in claim 4, McEwan does not displace platelet-poor plasma by moving the separating segment 18 toward the top of the chamber 12 through which the blood was transferred. To the contrary, the non-cellular component 42 is separated by pushing the separating segment 18 toward the bottom of the chamber 12. McEwan, col. 8, ll. 30-57. Similarly, Coleman displaces the lighter phase 24 (blood serum or plasma) by moving the plunger 26 toward the closed bottom of the container 20, not toward the top through which the blood was transferred into the container 20. Coleman, col. 6, ll. 52-61.

The element of "expelling said platelet-poor plasma through said second port of said plunger and said third port of said plunger rod into a waste bag attached to the plunger rod into a waste bag attached to the plunger rod" is also not disclosed, taught, or suggested in any of the applied references for at least the reasons provided in (C) above. Namely, the references do not disclose a plunger rod having a port or a waste bag attached to the plunger rod.

These are further reasons why claim 4 is allowable.

F. Conclusion with Regard to Claim 4

For at least these **five** reasons, independent claim 4 is allowable over McEwan, Coleman, Kelly, Furse, or a combination thereof. Claims 8, 10, 12, and 17, which depend from claim 4, are allowable for at least the same reasons.

Independent Claim 5

Independent claim 5 is directed toward a method of collecting and separating a patient's blood and recovering a platelet-rich concentrate. The method includes collecting the patient's blood using a needle set comprising a hollow needle having attached tubing and a fitting adapted to engage a first port in an elongated container fitted with a movable plunger having a second port therein. A valve positioned within the first port is opened, and the blood is transferred through the first port into the elongated container by moving the plunger away from the first port. The valve is closed, and the blood is centrifuged and separated into platelet-rich plasma and red blood cells, which are displaced by moving the plunger towards the first port and expelling the red blood cells into a waste bag through tubing attached to the first port. Platelet-poor plasma is separated by moving the plunger toward the first port and expelling the platelet-poor plasma through the third port of a plunger rod.

Claim 5 includes many of the claim elements of claim 4 discussed above, including the following:

- a needle set comprising a hollow needle and a fitting adapted to engage a first port;
- transferring the blood through the first port into the elongated container "by moving the plunger away from the first port";

- "displacing the red blood cells . . . from said container by moving said plunger towards said first port and expelling said red blood cells into a waste bag through tubing attached to said first port";
- displacing the platelet-poor plasma . . . from said container by moving said plunger towards said first port and expelling said platelet-poor plasma through said second port of said plunger and said third port of said plunger rod into a waste bag attached to the plunger rod".

Thus, claim 5 is allowable for at least the reasons discussed above with respect to claim 4.

Furthermore, claim 5 recites "opening a valve positioned within the first port" prior to transferring the blood into the container and "closing the valve" prior to centrifuging the blood. The Office Action concedes that "McEwan in view of Coleman . . . do not expressly disclose opening valves positioned within ports." Office Action, p. 4.

The Office Action then equates the first closure 14 of Furse with the valve of claim 5. As discussed in (B) above, however, the first closure 14 is "similar to **stoppers** of blood collection tubes known in the art" (*id.*, col. 6, ll. 56-57 (emphasis added)) and are "generally made of an elastomeric material such as bromobutyl rubber that reseals after being punctured by a needle or probe" (*id.*, col. 6, ll. 60-62). The portion of Furse cited by the Office Action in fact emphasizes this distinction, stating, "[T]he blood tube is normally evacuated and can be used to draw blood into first chamber 54 through a cannula **pierced through** the first closure 14 . . . ." *Id.*, col. 9, ll. 14-17 (cited by Office Action, p. 5) (emphasis added). Thus, far different from the valve of claim 5, which is opened and closed, the first closure 14 of Furse is punctured or pierced through. Thus, this element is not disclosed, taught, or suggested by Furse or any of the other applied references.

The Applicants respectfully submit that claim 5 and its dependent claims 9 and 13-15 are allowable for at least these reasons.

Independent Claim 16

Independent claim 16 is directed toward a method of collecting and separating a patient's blood and recovering a platelet-rich concentrate. The method includes collecting blood using "a needle set comprising a hollow needle and a fitting adapted to engage a first port in a container fitted with a movable plunger having a second port therein." The blood is transferred through the

first port into the container by moving the plunger away from the first port. The blood is centrifuged and separated into platelet-rich plasma and red blood cells, which are displaced by moving the plunger towards the first port and expelling the red blood cells through the first port. The platelet-rich plasma is centrifuged to separate a platelet-rich concentrate from a platelet-poor plasma. A hollow plunger rod having a third port therein is attached to the plunger to displace the platelet-poor plasma from the container "by moving said plunger towards said first port and expelling said platelet-poor plasma through said second port of said plunger and said third port of said plunger rod".

Claim 16 includes many of the claim elements of claims 4 and 5 discussed above, including the following:

- "a needle set comprising a hollow needle and a fitting adapted to engage a first port";
- transferring said blood through said first port into said container "by moving the plunger away from the first port";
- "displacing the red blood cells from said container by moving said plunger towards said first port and expelling said red cells through said first port";
- a second centrifuging act for "separating a platelet-rich concentrate from a platelet-poor plasma"; and
- "displacing the platelet-poor plasma from said container by moving said plunger towards said first port and expelling said platelet-poor plasma through . . . said third port of said plunger rod".

The Applicants respectfully submit that claim 16 is allowable because the applied references lack these elements, as provided above with respect to claims 4 and 5. Claim 18, which depends from claim 16, is believed to be allowable for at least these reasons.

Conclusion

It is the Applicants' belief that all of the claims are now in condition for allowance and action towards that effect is respectfully requested. The Applicants respectfully request that a timely Notice of Allowance be issued in this case. If there are any matters which may be resolved or clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney at the number indicated.

A check covering the fee for a one-month extension of time is enclosed. The Commissioner is authorized to deduct any other fee that may be required (except for payment of the issue fee) to Nixon Peabody, LLP, Deposit Account No. 50-4181, Order No. 247168-000158USD1. A duplicate copy of this paper is enclosed.

Dated: December 21, 2007

Respectfully submitted,

By _____

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